

Serial No.: 10/051,662

Our File No. 31140-B

REMARKS

Applicants first address the §112 rejections. Turning first to the issue of the rejection based on the claimed terms "estranes" and "gonanes," applicants direct the Examiner's attention to paragraphs 14-17 of the Hurteau Declaration. As explained there, it was well known in the art by 1997, that in the field of progestins, such there are subclasses of progestins known as estranes, gonanes and pregnanes. For example, the book entitled "*Progestins and Antiprogestins in Clinical Practice*," published in 2000, includes a chapter entitled "Pharmacology of Progestins: 17 Alpha Hydroxy Progesterone Derivatives and Progestins in the First and Second Generation." (hereinafter "Progestin Book").

Specifically, as noted in the Hurteau declaration and the Progestin Book, the "estrane progestins are derivatives of the testosterone molecule." (page 109 of the Progestin Book). Gonanes are the progestins that comprise the second and third generations of progestins. (See, e.g., the subsection of the Progestin Book entitled "*Gonane Progestins of the Second Generation*." (page 113)).

The next issue is the Vitamin D toxicity issue. The Examiner cites the Goodman and Gilman reference from 1975. Applicants direct the Examiner's attention to paragraphs 4-13 of the Hurteau declaration. Since the publication of the Goodman and Gilman reference in 1975, much has been discovered regarding the toxicity of Vitamin D. Dr. Hurteau explains this in his declaration. In fact, the Rodriguez application discloses a key teaching regarding the high dosing of Vitamin D to avoid toxicity. Specifically, the Rodriguez application teaches that one skilled in the art can avoid toxicity at high dosages by administering the higher dosages on a schedule that is less frequent than daily. Pages 16-17 of the Rodriguez application teach:

Prophylactic regimens for administration of Vitamin D compounds for normal female individuals and for those at increased risk of ovarian epithelial cancer can *include daily or*

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other periodic administration of Vitamin D compounds. It is contemplated that preferred regimens for prevention of ovarian cancer may comprise periodic administration of *relatively larger dosages* of Vitamin D compounds on *a monthly or less than monthly basis rather than more frequent administration*.... The advantage of a technique of using large doses of Vitamin D on an infrequent basis is that it may minimize the adverse calcemic effects of a more frequent administration of Vitamin D compounds.

This disclosure would enable persons skilled in the art to practice at dosages that Goodman and Gilman believed to be potentially toxic in 1975. (see paragraphs 8-10 of the Hurteau Declaration). Recent literature confirms what applicants taught in their specification, namely that higher dosages can be achieved by pulsing. (see paragraph 11 of the Hurteau Declaration).

Moreover, the present claims are composition claims that can be practiced based on the present disclosure without regard to hypercalcemic effects. But more importantly, doctors can monitor patients to avoid hypercalcemic effect based on well known techniques. (see paragraphs 9-10 and 13 of the Hurteau Declaration).

Applicants respectfully request that the Examiner withdraw the §112 rejections.

Applicants submit new claim 74 to address issues relating to the §103 rejection.

Applicants submit that the Need reference does not disclose such a contraceptive pill package and that such a claim would distinguish over Need.

As to the remaining rejections, applicants incorporate their prior arguments over the Need reference for the remaining claims and with respect to the Examiner's belief that certain claims are duplicative.

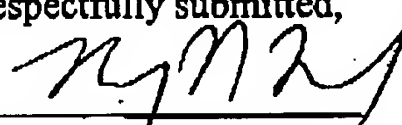
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Applicants request the opportunity to interview the Examiner on this application.

Applicants request allowance of one or more of the claims pending in the Application.

Dated: April 26, 2005

Respectfully submitted,



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